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UNITED STATES ARMY **ENVIRONMENTAL HYGIENE AGENCY**

ABERDEEN PROVING GROUND, MD 21018

PRELIMINARY ASSESSMENT OF THE RELATIVE TOXICITY OF CANDIDATE DISINFECTANT, FOOD SERVICE (CHLORINE-IODINE TYPE) NSN 6840-00-810-6396 AND TRICHLOROMELAMINE STUDY NO. 75-51-0195-84



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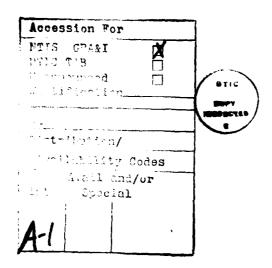
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Health Hazard	Acute Dermal	Potassium	
Disinfectant	Oral	Citric Ad	
Food Service Trichloromelamine	Skin Irritant Eye Irritant		lkyl Aryl Sulfonate um Dihydrogen Phosphate
Toxicity	NSN 6840-00-810		um Dinydrogen Phosphate ng Solutions
20. ABSTRACT (Coulders as rev			
The toxicity of the	candidate disin	fectant, food se	ervice (chlorine-iodine type)
			died by means of acute oral
			a pigs. The proposed "use"
			e found to be nonirritating to
			k from acute dermal or oral
			to the skin and eyes and was and dermal routes. Washing
			cts of the disinfectant.

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19. Rats
MIL-D-11309E
Rabbits
Guinea Pigs
Sensitization
Pouch Å
Pouch B
Ames Test
Draize Test



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Mr. Weeks/orl/AUTOYON DEPARTMENT OF THE ARMY U. S. ARMY ENVIRONMENTAL HYGIENE AGENCY 584-3980 ABERDEEN PROVING GROUND MARYLAND 21010

HSHB-OT/HP'

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SUBJECT: Preliminary Assessment of The Relative Toxicity of Candidate Disinfectant, Food Service (Chlorine-Iodine Type), NSN 6840-00-810-6396 and Trichloromelamine, Study No. 75-51-0195-84

Commander US Army Materiel Development and Readiness Command ATTN: DRCSG 5001 Eisenhower Avenue Alexandria, VA 22333

EXECUTIVE SUMMARY

The purpose, essential findings and conclusions of the inclosed report follow:

- a. Purpose. The candidate disinfectant, food service, (chlorine-iodine type) is intended for sterilization of mess gear under field conditions when hot water is not available. The Food Sciences Laboratory, US Army Natick Research and Development Center is engaged in attempts to register this disinfectant for field use with the Environmental Protection Agency (EPA). Information on the acute effects in animals was obtained to support the registration of this disinfectant in accordance with the Federal Insecticide. Fungicide and Rodenticide Act.
- b. Essential Findings. The proposed "use" solutions of the complete disinfectant mixture were found to be nonirritating to skin or eyes and does not pose a health hazard risk from acute dermal or oral exposures. The complete dry mixture was corrosive to the skin and eyes and was relatively toxic in concentrated solutions by oral and dermal routes. Washing of the eyes was found to reduce the corrosive effects of the disinfectant.
- c. <u>Conclusions</u>. Based on the current study, the recommended "use" solution concentration of the proposed disinfectant has no potential for causing acute injurious effects. Concentrated solutions of this mixture are corrosive and should be used with care. Appropriate personal protection for handling strong acids and bases should be used.

FOR THE COMMANDER:

1 Incl

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JOEL C. GAYDOS

Colonel, MC

Director, Occupational and Environmental Health

HODA (DASG-PSP) wo incl

Cdr, TROSCOM Cdr, HSC (HSPA-P)

Comdt, AHS (HSHA-IPM)

Cdr, NARADCEN (DRXNM-YPB) Cdr, MEDDAC, Ft Devens (PVNTMED Actv)(2 cy) Cdr, WRAMC (PVNTMED Actv)

C. USAEHA-Rgn Div North



DEPARTMENT OF THE ARMY U.S. ARMY ENVIRONMENTAL HYGIENE AGENCY ABERDEEN PROVING GROUND, MARYLAND 21010

MEPLY TO ATTENTION OF

HSHB-OT/WP

PRELIMINARY ASSESSMENT OF THE RELATIVE TOXICITY OF CANDIDATE DISINFECTANT, FOOD SERVICE (CHLORINE-IODINE TYPE)
NSN 6840-00-810-6396 AND TRICHLOROMELAMINE*†
STUDY NO. 75-51-0195-84

- 1. AUTHORITY. Letter, DRXNM-YPB, US Army Natick Research and Development Command, 1 July 1976, subject: Eye and Skin Irritation Tests for Disinfectant Food Service (Chlorine-Iodine Type), NSN 6840-00-810-6396 and Trichloromelamine (TCM) with indorsement thereto.
- 2. REFERENCE. See Appendix A for a listing of references. The Biliography is listed in Appendix KK.
- 3. PURPOSE. Animal studies were conducted to acquire information concerning the acute relative toxicity of subject disinfectant and its major constituents. These data were furnished to the Environmental Protection Agency (EPA) by the US Army Natick Research and Development Center (NARADCEN), Natick, Massachusetts (references 24 and 25), in preparation for the registration of the subject disinfectant in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (reference 22).

4. BACKGROUND.

a. Sanitizing Agent.

(1) The subject food service disinfectant is intended for sterilization of mess gear under field conditions and only when hot water rinse is not available. The materials for preparing this solution rinse are furnished in a double compartmented pouch labeled Pouch "A" and Pouch "B". These pouches contain chemicals sufficient for preparing 25 gallons of water containing approximately 160 mg/L of chlorine and 300 mg/L of iodine. The ingredients of the pouches as percent by weight are as follows:

Pouch "A"	
Trichloromelamine (TCM)	19.3
Anhydrous citric acid	27.8
Sodium alkyl aryl sulfonate Anhydrous monosodium	8.2
dihydrogen phosphate	6.1
Pouch "B" Potassium fodide (KI) USP	28.6

^{*} In conducting the studies described in this report, the investigators adhered to the "Guide for the Care and Use of Laboratory Animals", US Department of Health, Education and Welfare Publication No. NIH 78-23. † The experiments reported herein were performed in animal facilities fully accredited by the American Association for the Accreditation of Laboratory Animal Care.

[†] The test pouches were formulated by the Chemical Compounding Company, Riverhead, New Jersey, and identified as Lot 0611-1. The TCM (Lot 409R) was produced by Union Camp Corporation, Wayne, New Jersey, in accordance with military specification MIL-D-11309E and by procedures originally published by Wallace and Tierman Inc., Belleville, New Jersey.

- (2) The directions for use of the disinfectant are based on the treatment of 100 sets of mess gear. The contents of Pouch "A" and Pouch "B" are dissolved in a container holding 25 gallons of water. This procedure is repeated with a second container. The procedure for sterilizing mess gear is to first wash them clean in a scrub container, rinse twice, once in the first container of disinfectant solution and a final rinse in the second container of disinfectant solution. The mess gear is then air dried.
- (3) The pouches can also be used for preparation of solutions for disinfectant of fresh vegetables and fruits. Directions for preparation of the solutions are different from those for the mess gear rinse. First, the fruits and vegetables are washed in a solution made by dissolving the contents of the two pouches into 20 gallons of water. This solution yields approximately 225 mg/L of chlorine and 300 mg/L of iodine. After washing, the fruits and vegetables are completely immersed for 10 minutes in a separate fresh solution prepared as above. After 10 minutes of immersion, the fruits and vegetables are rinsed thoroughly in potable water. This procedure has not been approved by the Food and Drug Administration (FDA) for use by the general public.
- (4) The use of TCM in sanitizing solutions has been recognized by the FDA as being safe under some conditions. Aqueous solutions containing trichloromelamine and either sodium lauryl sulfate or dodecylbenzene-sulfonic acid has been approved for use on food-processing equipment and utensils and on other food-contact articles as specified in 21 CFR 178.1010. This solution may be used on beverage containers (except milk containers or equipment). However, these solutions shall provide not more than sufficient TCM to produce 200 parts per million of available chlorine and either sodium lauryl sulfate at a level not in excess of the minimum required to produce its intended functional effect or not more than 400 parts per million of dodecylbenzene-sulfonic acid [21 CFR 121.2547(b)(10) and (c)(7)]. Sac's hazard analysis of TCM states that the details of its toxicity are unknown, although animal experiments indicate a low order of oral toxicity. The mouse oral LD 50 has been reported as 490 mg/kg². The TCM solutions are strong oxidizing agents and when in contact with organic matter, would be reduced to melamine. Depending, therefore, on the use of TCM, the toxicity of melamine might be considered in the overall hazard evaluation of TCM. A moderate number of investigations with melamine suggest that it may have a low order of biological activity. I
- b. Toxicity of TCM. The results from a carcinogenicity study in rats and mice by the National Cancer Institute (NCI) are still being evaluated, but preliminary evidence indicates that it causes a significant number of bladder calculi with an increase in the incidence of urinary bladder neoplasms in male rats². No evidence of bladder stones or of tumor formation was found in female rats or in male/female mice².

c. Toxicity of Other Ingredients. The acute toxicities of KI and of citric acid are very low with an oral LDL $_0$ of 1900 mg/kg for KI and a LD50 of 5000 mg/kg for citric acid in mice. Sodium alkyl aryl sulfonate and monosodium dihydrogen phosphate have not been extensively studied with only an intramuscular rat LD50 of 250 mg/kg being reported for the latter chemical.

5. MATERIALS AND METHODS.

a. Materials.

- (1) The materials under study were obtained from the Food Sciences Laboratory, NARADCEN. The composition of the two pouches were described in paragraph 4, this report. The various materials tested in animals were as follows:
 - (a) Trichloromelamine dry and as a wet paste.
 - (b) Potassium iodide dry and as a wet paste.
- (c) Disinfectant mixture prepared as the aqueous "use" solution complete with KI for use with mess kits.
 - (d) Disinfectant mixture complete with KI as a dry brown powder.
 - (e) Disinfectant mixture complete with KI as a wet paste.
 - (f) Disinfectant Pouch "A" formulation as a dry white powder.
 - (g) Disinfectant Pouch "A" formulation as a wet paste.

Solutions and wet paste formulations were prepared with distilled water and used on the day of preparation. Details of amounts and volumes will be described separately for each test.

(2) Toxicological evaluations of the sanitizing products were conducted using New Zealand White rabbits for skin and eye studies, Hartley guinea pigs for a sensitization study and Sprague-Dawley, Wistar derived rats for determination of acute oral toxicity. One strain of yeast Saccharomyces cerevisiae and five strains of Salmonella typhimurium were used in evaluating the mutagenic potential of trichloromelamine. All animals were maintained on commercial chow and water ad libitum with a 12-hour, light-dark sequence. Ambient conditions were $24^{\circ}\text{C} + 2^{\circ}\text{C}$ and 40-60 percent relative humidity. Rabbits were housed in individual wire cages, while rats and guinea pigs were housed in groups of four to six in hanging wire gang cages.

(3) The results from the animal toxicity studies were categorized by the use of the hazard indicator table published in 40 CFR 162. They are described in Table 1.

TABLE 1. HAZARD INDICATORS

Hazard Indica	hane	TOXICITY CATEGORI	ES	
	i	II	III	IV
Oral LD50	Up to and in- cluding 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LD50	Up to and in- cluding 0.2 mg/L.	From 0.2 thru 2 mg/L.	From 2 thru 20 mg/L.	Greater than 20 mg/L.
Dermal LD50	Up to and in- cluding 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.
Eye effects	Corrosive, corneal opacity not reversible within 7 days.	Corneal opacity reversible with-in 7 days; irri-tation persist-ing for 7 days.	No corneal opa- city; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irrita- tion at 72 hours.	Moderate irri- tation at 72 hours.	Mild or slight irritation at 72 hours.

b. Methods.

⁽¹⁾ Primary Skin Irritation Studies. The test for acute primary skin irritation was performed to evaluate the potential for local toxic effects of chemicals expected to come in contact with the skin. It refers to one period of topical application for 24 hours (the exposure period) and an observation period of 7 days. In these studies, the irritant responses from either 0.5 gm or 0.5 mL of the disinfectant materials were evaluated following a single 24-hour application to occluded intact and abraded skin of New Zealand white rabbits. The Draize⁴ scoring system (Appendix B) was used for evaluation of the skin reactions. A list of the test substances, conditions of application and the responses are found in Table 2 of the results section.

- (2) Eye Irritation Studies. The test for acute eye irritation was performed to evaluate the toxicity of liquids and solids to ocular tissues of laboratory animals. The test determines the potential of a substance to produce injury to the human eye. It refers to one period of application into the conjunctival sac of one eye of each rabbit and an observation period of 7 days. In these studies, the eye was either washed out 20 seconds after application with warm distilled water for 1 minute or left unwashed. The Draize scoring system (Appendix C) was used for the evaluation of eye responses. A list of the test substances, conditions of application and the responses are found in Table 3 of the results section.
- (3) Acute Oral and Dermal Toxicity Studies. Acute toxicity studies are performed to determine the adverse effects occurring within a short period of time following a single dose of a substance. This type of study identifies the relative toxicity of a compound, investigates its mode of action and specific toxic effect, and determines the existence of species differences. The most frequently used acute toxicity test involves determination of the median lethal dose (LD50) of the compound. The LD50 is defined as a statistically derived expression of a single dose of a material that can be expected to be lethal to 50 percent of the treated animals (reference 3). In the present study, single doses of compound are administered to male rats by gavage and to male rabbits by 24-hour skin application under an occluded wrap. A 14-day observation period is used to observe death or clinical signs with animals being weighed at 1, 3, 7 and 14 days after exposure. A gross necropsy is performed on all survivors. Calculation of the LD50 is performed by the Method of Bliss as described by Finney⁵. A list of the test substances, conditions of application and the responses from the rat oral studies and the rabbit dermal studies are found in Tables 4 and 5 of the results section, respectively.
- (4) Sensitization Studies. Skin sensitization is a phenomenon wherein the responses obtained by exposing the animal to a chemical through skin contact over a prolonged period of time are significantly greater than that obtained from a single exposure. The test procedure is based on the studies of Landsteiner and used to predict possible strong skin sensitizing chemicals. The animal used is the male Hartley strain albino guinea pig. The test was conducted with 10 guinea pigs given intradermal (ID) injections of a 0.1 percent solution (w/v) of the chemical in saline. The injections were given every other day (for 3 weeks), after which the animals were rested for 2 weeks and then challenged with one ID injection of the same compound and concentration. A positive control dinitrochlorobenzene (DNCB), was run concurrently with the test substances. The substances tested were TCM, complete disinfectant mixture, and pouch "A."

(5)-Mutagenicity Plate Assay§. The objective of this study was to evaluate TCM for genetic activity in microbial assays with and without the addition of mammalian metabolic activation preparations. One strain of yeast Saccharomyces cerevisiae (D4) and five strains of Salmonella typhimurium (TA-1535, TA-1537, TA-1538, TA-98 and TA-100) were used in evaluating mutagenic potential. Trichloromelamine was tested directly and in the presence of liver microsomal enzyme preparations from rats pretreated with Aroclor® 1254. The compound was tested over a series of concentrations ranging from 0.1 microgram to 500 microgram/plate. These concentrations were selected so that there was either quantitative or qualitative evidence of some chemically induced effects at the high dose level. The low dose was below a concentration that demonstrated any toxic effect.

6. RESULTS.

a. Skin Irritation Studies. The potential for primary skin irritation was tested by 24-hour application of the material to the intact and abraded skin of six rabbits. The dry materials, except for the disinfectant mixture, caused little skin irritation. The dry complete disinfectant mixture caused severe primary irritation of the intact skin and of the skin surrounding an abrasion, and in addition produced necrosis and vesiculation at 72 hours. The KI pastes produced mild or slight irritation, the TCM and contents of Pouch "A" produced moderate irritation, and the complete disinfectant mixture produced severe primary irritation with necrosis and vesiculation. The aqueous "use" disinfectant solution caused no irritant responses. Results from each application are shown in detail in Appendices D thru L. A summary of the skin responses from the test substances, conditions of application and EPA toxicity categories are shown in Table 2 as follows:

[§] Work performed under contract by Litton Bionetics, Kensington, MD (LBI Project No. 20838).

[◆] Aroclor is a registered trademark of Monsanto Chemical Co., 800 N Lindberg Boulevard, St. Louis, Missouri. Use of a trademarked name does not imply endorsement by the US Army, but is intended only to assist in identification of a specific product.

TABLE 2. PRIMARY SKIN EVALUATION STUDY SHOWING THE TEST SUBSTANCES AND CONDITION PER APPLICATION WITH RESPONSE

Substance Condition of Application	Response	EPA Category
Trichloromelamine		
<pre>0.5 gm dry white powder 0.5 gm wet paste compound in 0.5 mL distilled water</pre>	very slight irritation moderate irritation	III
Potassium Iodide		
0.5 gm dry white crystalline powder	slight irritation	IV
0.5 gm wet paste of compound in 0.5 mL distilled water	slight irritation	IV
Disinfectant		
0.5 mL complete aqueous "use" solution with KI	no irritation	IA
0.5 gm dry brown powder of complete mixture with KI	severe irritation	II
0.5 gm wet paste of complete mixture in 0.5 mL distilled water	severe irritation	11
Pouch "A" Formulation		
0.5 gm dry powder mixture 0.5 gm wet paste of Pouch "A" in 0.5 mL distilled water	slight irritation moderate irritation	III

b. Eye Irritation Studies. The ability of the disinfectant materials for causing ocular damage was studied by application of each material to the eyes of each of 12 rabbits. The material was washed out from 6 rabbits after 20 seconds and allowed to remain overnight in the others. Dry TCM, Pouch "A" and complete disinfectant mixture caused corrosive corneal opacity not reversible within 7 days. Dry KI caused no corneal opacity with the slight

conjunctival irritation clearing within 7 days. The "use" solution of the complete disinfectant mixture caused no irritation to the eye. Washing the eye after application helped to reduce the corrosive response in all cases except for KI where washing increased the irritation. Results from each application are shown in detail in Appendices M thru V. A summary of the eye responses from the test substances, conditions of application and EPA toxicity categories are shown in Table 3.

TABLE 3. EYE IRRITATION EVALUATION STUDIES SHOWING THE TEST SUBSTANCES AND CONDITIONS PER APPLICATIONS WITH RESPONSE

Substance Condition of Application	Unwashed or Washed	Response	EPA Category
Trichloromelamine			
0.1 gm dry white powder;	unwashed washed	corrosive moderate reversible injury	I
Potassium Iodide			
0.1 gm dry white crystalline powder	unwashed	moderate conjunctival irritation	III
,	washed	mild reversible injury	II
Disinfectant			
0.1 ml complete aqueous "use" solution with KI	unwashed	no injury	IA
ase solution with ki	washed	no injury	IV
0.1 gm dry brown powder of complete	unwashed	corrosive	I
mixture with KI	washed	moderate reversible cornea injury	II
Pouch "A" Formulation			
0.1 gm dry powder mixture	unwashed	corrosive	I
	washed	moderate reversible cornea injury	II

c. Acute Toxicity - Rats.

(1) Oral. In the acute oral toxicity studies, the test compounds were dissolved in distilled water for delivery to rats. Solutions of TCM and KI were used at a concentration of 500 mg/mL, the complete disinfectant at 1.7 mg/mL and 500 mg/mL and Pouch "A" at 300 mg/mL. The solutions were administered by stomach tube to mature male rats, and the LD50's were calculated after a 14-day observation period. Signs in rats at lethal dosages were ataxia, weakness, convulsions and red exudate around the eyes with all compounds except the disinfectant "use" mixture, where no signs were seen. Results from each study are shown in detail in Appendices W thru AA. A summary of the rat oral LD50's from the various test substances, conditions of application and EPA toxicity categories are shown in Table 4.

TABLE 4. ACUTE RAT ORAL TOXICITY STUDIES SHOWING THE TEST SUBSTANCES, CONDITIONS PER APPLICATION AND LD50 VALUES

Substance	Response LD50	EPA
Condition of Application	(95% C.L.)	Category
Trichloromelamine		
concentration - 500 mg/mL	690 mg/kg (560-870 mg/kg)	III
Potassium Iodide concentration - 500 mg/mL	4800 mg/kg (4200-5500 mg/kg)	111
Disinfectant complete aqueous "use" solution with KI		
concentration 1.7 mg/mL	> 22 mL/kg (> 37 mg/kg)	
complete aqueous solution with KI concentration - 500 mg/mL	2400 mg/kg	111
500 mg/mc	(2000-2800 mg/kg)	111
Pouch "A" Formulation concentration - 300 mg/mL	3000 mg/kg	111
Concentration = 300 mg/mL	(2500-3600 mg/kg)	111

(2) Acute Dermal Toxicity - Rabbits. The test compounds in acute dermal toxicity studies were administered in several different aqueous conditions. The test compounds when applied as a solid were mixed into a paste with equal quantities of distilled water (w/v). The complete disinfectant mixture was applied as a 2.5 percent w/v solution while TCM was used as a 9 percent solution. Signs in rabbits at lethal dosages were tremors and nasal discharge. Primary skin irritation progressing to necrosis was seen at all dosage levels. There were no gross changes in organs and tissues from decedents or survivors of rabbits receiving TCM or the complete disinfectant (25 mg/mL). Rabbits that died following application of the complete disinfectant as a wet paste showed fatty livers or early cirrhotic changes. Kidneys from these rabbits were fatty or diffusely hemorrhagic with clots in the pelvic area. Rabbits exposed to KI had caseous material in the urinary bladder with thickening of the wall. Pouch "A" also caused kidney effects, and free blood in the abdominal cavity with fibrin tags on the viscera, but no evidence of perforated viscera. Details of these studies are found in Appendicies BB thru GG. The rabbit dermal LD50 values, conditions of application and EPA catagories are summarized in Table 5 as follows:

TABLE 5. ACUTE RABBIT DERMAL TOXICITY STUDIES SHOWING THE TEST SUBSTANCES, CONDITIONS PER APPLICATION AND LD50 VALUES

Substance Condition of Application	Response LD50 (95% C.L.)	EPA Category
Condition of Apprication	(93% C.C.)	category
Trichloromelamine		
wet paste	10 g/kg (8.4-11.9 g/kg)	III
solution in distilled water- 90 mg/mL		III
Potassium Iodide		
wet paste	3.7 g/kg (3.0-6.7 g/kg)	III
Disinfectant		
complete mixture - wet paste	2.6 g/kg (1.1-6.2 g/kg)	III
complete mixture concen- tration - 25 mg/mL	> 31.6 ml/kg (> 790 mg/kg)	
Pouch "A" Formulation wet paste	2.7 g/kg (1.2-5.9 g/kg)	111

- (3) Sensitization Studies. The inherent sensitization potential was studied in guinea pigs with 10 0.1 mL ID injections at a 0.1 percent solution in saline of TCM, complete disinfectant mixture with KI and the contents from Pouch "A" formulation of the disinfectant. A 3-week exposure period followed by a 2-week rest, then challenge with a single dose of the sensitizing solution, showed that the three test compounds produced no recognizable sensitization reactions. A concurrent group of guinea pigs was similarly tested using the known sensitizer dinitrochlorobenzene (DNCB). At challenge DNCB produced definite sensitization reactions in all treated animals. Details of the sensitization studies are shown in Appendices HH thru JJ.
- (4) Mutagenic Screen. Trichloromelamine was tested for mutagenic activity using the standard Ames overlay method. Solutions were prepared in deionized water with the dose range employed ranging from 0.1 microgram to 500 micrograms per plate. It was toxic to all organisms at doses higher than 100 micrograms per plate. Positive and solvent controls using both directly active positive chemicals and those that require metabolic activation were run with each assay. The results were presented as revertants per plate for each indicated strain employed in the assay. Test results in the absence or the presence of the rat liver activation were all negative.

7. DISCUSSION.

- a. Our studies have demonstrated dose dependent acute lethal effects resulting from exposure of animals to the concentrated disinfectant food service mixture and its components. These studies also showed that low concentration of the disinfectant at 2.5 percent and at "use" levels are not lethal and are nontoxic by the oral and dermal routes of administrations.
- b. The physical condition of the materials was a major variable in skin irritation studies. Different responses of the skin were seen between application of the materials in a dry state or as a wet paste. The dry materials, except for the total disinfectant mixture, were less irritating to the skin than the wet. Translated to operating conditions, serious skin irritation could result from handling the wet paste or concentrated material of the disinfectant mixture. Interestingly the "use" solution was found to be noninjurious causing no skin or eye irritation responses.
- c. The use of water to wash the material from the eyes was of some benefit in reducing the corrosive effect of the materials. Eye rinses should be available in the areas where these materials are handled and rinsing should be actively pursued in cases of accidental eye exposure.
- d. The lack of gross changes in organs and tissues at necropsy of rabbits exposed to a 2.5 percent solution of the complete disinfectant is encouraging and reflects and reinforces the noninjurious nature of this solution. These findings also parallel and support the nonirritant skin and eye results obtained from the "use" mixture studies.
- e. Overall, the data from our acute studies show that the "use" solution mixture does not pose a hazard from skin, eye or ingestion exposure. However, care should be taken to avoid eye or skin contact from the concentrated dry mixture, wet concentrates or pastes of these materials.

- f. Although the acute problem with the disinfectant has been addressed, there are no data on the chronic effects of the mixture or of the major ingredient TCM. In addition, information on the environmental persistence of TCM is lacking and no occupational standard for exposure to TCM has been established by the Occupational Safety and Health Administration.
- g. Trichloromelamine has never been evaluated for carcinogenicity. The chemical is a reactive compound with hydrolysis to melamine and hypochlorous acid expected to be the dominant reaction of the compound. As a result of the melamine findings, however, there may be some potential for TCM to be associated with the production of bladder calculi. The assumed similarity in metabolism of TCM should be considered in planning future long-term animal studies. Emphasis should be on examining the relationship between the projected exposure to TCM and potential hazard from serious toxicological consequences.

Warn N Worldy MAURICE H. WEEKS

Chief, Toxicology Division

TIMOTHY WE ANDT, M.D., M.P.H.

MAJ. MC

Assistant for Chemical Warfare and Health Hazard Evaluation

APPENDIX A

REFERENCES

- 1. Title 21, Code of Federal Regulations (CFR), 1982 rev, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies.
- 2. Title 40, CFR, 1982 rev, Part 162, Regulations for the Enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act.
- 3. Toxicology Division Procedural Guide, US Army Environmental Hygiene Agency (USAEHA), 1972, revised 1976.
- 4. Letter, HSE-LT, this Agency, 14 December 1976, subject: Toxicity Data on Disinfectant Food Service, NSN 6840-00-810-6396, USAEHA Study Number 51-0924-76.
- 5. Letter, HSE-LT, this Agency, 20 April 1977, subject: Toxicity Data on Disinfectant Food Service, NSN 6840-00-810-6396, USAEHA Study Number 51-0924-76.

APPENDIX B

SCALE FOR SCORING SKIN LESIONS

DRAIZE SYSTEM

1.	ERYTHEMA AND ESCHAR FORMATION.		
	a. No erythema	0	
	b. Very slight erythema (barel	y perceptible) 1	
	c. Well defined erythema	2 3	
	 d. Moderate-to-severe erythema 		
	e. Severe erythema ("beet" red eschar formation injurious	ness to slight in depth) 4	
	f. Possible total erythema sco		
2.	EDEMA FORMATION.	•	
	a. No edema	. 0	
	b. Very slight edema (barely p	erceptible) 1	
	c. Slight edema (edges of area		
	by definite raising)	2	
	d. Moderate edema (edges raise	4	
	approximately 1 mm)	3	
	e. Severe edema (raised more t	han 1 mm and	
	extending beyond area of ex	posure) 4	
	f. Possible total edema score	4	
3.	POSSIBLE TOTAL SCORE FOR PRIMAR	Y IRRITATION. 8	

APPENDIX C

SCALE FOR SCORING OCULAR LESIONS

DRAIZE SYSTEM

	•
1.	Cornea
a.	Opacity-degree of density (most dense area taken for reading) No opacity
b.	Area of cornea involved One quarter (or less) but not zero
Sco	re = (a) x (b) x (5) = Total max score = 80
2.	Iris
a.	Values Normal
Sco	re = (a) x 5 Total max score = 10
3.	Conjunctivae
a.	Redness (refers to palpebral and bulbar conjunctivae excluding cornea and iris) Vessels normal
b.	Chemosis
	No swelling
c.	Discharge
Sco	No discharge

APPENDIX D

consound: Trichl	Trichloromelamine							NSU	USAEHA STUDY NO. 75-51-0195-84
Pritany skin effects Kem Zealand White Rabbits	crs	TOXI	ICITY IV	CAT	TOXICITY CATEGORY IV	* *	·	CONDITIONS - Trichloromel application	CONDITIONS - Dry Trichloromelamine - Single 24-hour application of 0.5 g dry white powder per
-	Time of	L	8	Response					
	Observation	L	वृद्ध	Rabbit No.	ۏ	1			
	Hours		~	~	4	2	و.	Mean Score	Comments
Erythema & Eschar					-				•
Intact Skin	*	0	0	•	0	0	0	0.00	Category IV compounds are
Intact Skin	. 72	0	7	0	0	•	0	0.17	compounds producing none, mild
Abraded Skin	77	0	0	0	0	0	0	00.00	or slight irritation at 72 hours.
Abraded Skin	22	0	<u> </u>	_ `	Sugar	0 Subtota	0.4	0.50	·
Edema Formation									
Intact Skin	24	0	٥	0	0	0	0	00.0	
Intact Skin	72	0	0	0	0	0	0	0.0	
Abraded Skin	77	7	0	0	0	7	0	0.33	
Abraded skin	F	0	<u>-</u>	_	-3. 5T	0 Subtot Total	o 1	0.17	
								•	. •
				4	1	1			

Skin reactions are evaluated using Draize scoring systems. Draize, J.H., Woodward, G. and Calvary, H.O., Methods for the Study of Irritation of Toxicity of Substances Applied Topically to the Skin and Mutous Membranes, J. Pharmacol and Exp Therap., 82: 777, 490, 944. * 40 CFR 162

APPENDIX E

corround: Trichloromelanir	romelamine							USA	USAEHA STUDY NO. 75-51-0195-84
PRIMARY SKIN EFFECTS IEW ZEALAND WHITE RABBITS	crs	TOXICITY CATEGORY*	CITY	r care	SOOR			CONDITIONS - Trichloromela	CONDITIONS - Wet paste Trichloromelamine - Single 24-hour application of 0.5 g compound in 0.5 ml
		_						Nater.	
	Observation		Raiob Bobb	Rabbit No.			T		
	Hours	4	7	m	4	5	٥	Mean Score	Comments
Erythema & Eschar						•			
Intact Skin	24	1	7	7			· (f)	1.67	Category III compounds are
Intact Skin	72	7	7	7	0	_	-	0.83	compounds producing moderate
Abraded Skin	*	0	~	7	7	_	_	1.16	irritation.
Abraded Skin	72	•	- -	-	1 Sul	0 Subtota	- 겉	3.99	
Edena Formation									
Intact Skin	. 54	~	-	-	•	_	7	1.16 /	
Intact Skin	72	٥	•	0	0	0	-	0.17	
Abraded Skin	7.	0	-	~	7	-	-	0.83	
Abraded Skin	22	<u> </u>	-	0	Sul To	0 Subtota	০ ব্ব	2.16 6.15	
					J		-		

Skin reactions are evaluated using Draize scoring systems. Draize, J.H., Woodward, G. and Calvary, H.O., Methods for the Study of Irritation of Toxicity of Substances Applied Topically to the Skin and Mucous Membranes, J. Pharmacol and Exp Therap., 82: 777, 490, 944. *40 CFR 162

APPENDIX F

CC::PC::ID: Potassium Iodide	lum Iodide							USA	USAEHA STUDY NO. 75-51-0195-84
PPINARY SKIN EFFECTS VEW ZEALAND WHITE	crs	TOXI	CIT	CAT	TOXICITY CATEGORY	* *		CONDIT	CONDITIONS - Dry Potassium Iodide (KI) - Single 24-hour
RABBITS					^1			applica powder	application of 0.5g dry white crystalline powder per skin application site.
	Time of	_	Res	Response	9				
	Observation		Rabb	Rabbit No.	٥				
•	Hours		2	3	4	2	9	Mean Score	Comments
Erythena & Eschar									
Intact Skin	24	~	0	-	0		0	0.67	Category IV compounds are
Intact Skin	72	0	0	-	0	0	0	0.17	compounds producing none, mild
Abraded Skin	24	0	7	~	0	7	0	1.00	or slight irritation at 72 hours.
Abraded Skin	22	0	<u> </u>	•	- o	0 Subtota	cal o	1.84	•
Edema Formation									
Intact Skin	24		0	. 0	0	0	c	0.17	
Intact Skin	27	0	0	0	0	0	0	0.0	
Abraded Skin	24	0	0	0	0	-	0	0.17	
Abraded Skin	<u> </u>	<u> </u>	0	0	- S & B	0 Subtota Total	tal tal	0.17 0.51 2.35	
		4		1	1	1			

Skin reactions are evaluated using Draize scoring systems. Draize, J.H., Woodward, G. and Calvary, H.O., Methods for the Study of Irritation of Toxicity of Substances Applied Topically to the Skin and Mucous Membranes, J. Pharmacol and Exp Therap., 82: 777, 490, 944. . 40 CFR 162

APPENDIX G

CC:4PCU:1D: Potassium Iodid	lum Iodide							USA	USAEHA STUDY NO. 75-51-0195-84
PRIMARY SKIN EFFECTS HEW ZEALAND WHITE	crs	TOXI	CITY	TOXICITY CATEGORY	EGOR	*		CONDIT	CONDITIONS - Wet paste Potassium Iodide (KI) - Single 24-hour
RABBITS			IV					applic water.	application of 0.5 g compound in 0.5 ml water.
	Time of		Res	Response					
•	Observation	_	Rabo	Rabbit No.					
	Hours		~	7	4	2	٥	Mean Score	Comments
Erythema & Eschar									
Intact Skin	24	0	•	0	0	0	н	0.17	Category IV compounds are
Intact Skin	72	0	0	7	0	0	0	0.17	compounds producing none, mild
Abraded Skin	. 24	1	0	7	0	7	0	0.50	or slight irritation at 72 hours.
abraded Skin	. 72	0	7	0	7	7	0	0.50	•
			•	•	Su	Subtotal	18:	1.34	•
Edema Formation						 _			
Intact Skin	24	0	0	0	0	0	0	0.00	
Intact Skin	72	0	0	0	0	0	0	0.00	
Abraded Skin	24	0	0	0	0	0	0	8.0	
Abraded Skin	22	•	_	0	Su -	0 Subtota Total	o Eal	0.33 0.33 1.67	
									•

Skin reactions are evaluated using Draize scoring systems. Draize, J.H., Woodward, G and Calvary, H.O., Methods for the Study of Irritation of Toxicity of Substances Applied Topically to the Skin and Mucous Membranes, J. Pharmacol and Exp Therap., 82: 777, 490, 944. • 40 CFR 162

APPENDIX H

compound: Aqueous	Aqueous (use) solution complete disinfectant mixture	n co	m)let	e d	sint	Secta	int m		USAEHA STUDY NO. 75-51-0195-84
PRIMARY SKIN EFFECTS	crs	TOXICITY CATEGORY *	CITY	12	EGGR	*		Disinfectant mi	Condition - Wet Disinfectant mixtura - Single 24-hour appli-
RABBITS			Ν					tion o	cation of 0.5 ml aqueous disinfectant solution. Dry disinfectant mixture diluted
	Time of		Res	Response				mixture	mixture ml water)
•	Observation		Rabb	Rabbit No.					
	Hours	-	~	m	4	2	٥	Mean Score	Comments
Erythena & Eschar	٠	•							
Intact Skin	24	0	0	0	0	0	•	0.0	Category IV compounds are
Intact Skin	72	0	0	0	0	0	•	0.0	compounds producing none, mild or
· Abraded Skin	24	0	0	0	0	0	0	0.0	slight irritation at 72 hours.
Abraded Skin	72	0	•	-	•	0	0	0.0	
			•	-	S.	Subtota	al	0.0	
Edema Formation									
Intact Skin	24	0	•	0	0	0	0	0.0	
Intact Skin	72	0	٥	0	0	0	0	0.0	
Abraded Skin	5	0	0	0	0	0	0	0.0	
Abradad Skin	72	<u> </u>	-	0	- s c	0 C Subtotal Total	0 të:	0000	

Skin reactions are evaluated using Draize scoring systems. Draize, J.H., Woodward, G and Calvary, H.O., Methods for the Study of Irritation of Toxicity of Substances Applied Topically to the Skin and Muçous Membranes, J. Pharmacol and Exp Therap., 82: 777, 490, 944. * 40 CFR 162

APPENDIX I

composition desinfectant mixture, complete with KI, Dry	ctant mixture,	compl	lete	with	, KI,	נים		USN	USAEIIA STUDY NO. 75-51-0195-84
PAINARY SKIN EFFECTS NEW ZEALAND WHITE	CTS	roxi	CITY	TOXICITY CATEGORY	EGOF	* XX		CONDIT	CONDITIONS - Dry Disinfectant mixture - Single 24-hour
RABBITS				11				application mixture per	application of 0.59 brownish dry complete mixture per skin application site.
	Time of		Res	Response	ø				
	Observation	_	Rabbit	it N	No.				
	Hours	1	7	6	4	2	9	Mean Score	Comments
Erythena & Eschar						***************************************			
Intact Skin	24	7	7	4	7	4	п	2.33	Category [] compounds are compounds
Intact Skin	72	4	7	4	0	4	0	2.33	producing severy primary irrita-
Abraded Skin	24	3	4	4	4	m	4	3.67	tion of the intact skin and of the
Abraded Skin	72	<u>e</u>	4	~	7	7	7	2.50	skin surrounding an abrasion and
				_	S	Subtotal	ta]	10.83	in addition producing necrosis
Edema Formation									and vestcutation at 12 nouts.
Intact Skin	. 24		3	m	0	m	0	1.67	
Intact Skin	72	0	~	9	0	4	0	1.67	
Abraded Skin	24	3	7	7	7	7	~	2.17	
Abraded Skin	72	8	0	7	6	-	0	1.33	
				•	S.	Subtotal Total	ra i	6.84	

Skin reactions are evaluated using Draize scoring systems. Draize, J.H., Woodward, G. and Calvary, H.O., Methods for the Study of Irritation of Toxicity of Substances Applied Topically to the Skin and Mucous Membranes, J. Pharmacol and Exp Therap., 82:777, 490, 944. 40 CFR 162.

APPENDIX J

TOXICITY CATEGORY TOXICITY CATEGORY TOXICITY CATEGORY TOXICITY CATEGORY Time of	componio: Disinfect	Disinfectant mixture, complete with KI	compl	ete	with	ΚΙ			USA	USAEHA STUDY NO. 75-51-0195-84
Time of Rabbit No. Hours 1 2 3 4 5 6 Mean S. 24 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4	LYARY SKIN EFFECT W ZEALAND WHITE WABBITS		TOXIC	:ITY	CATE II	GORY	*		CONDITIONS - Disinfectant application water	CONDITIONS - Wet paste. Disinfectant mixture - Single 24-hour application of 0.5g mixture in 0.5 ml water.
Abours 1 2 3 4 5 6 Hours 1 2 3 4 5 6 24 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4		Time of		Rest	onse			-		
24 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4		Observation		dces	t No					
24 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4		Hours		~	F	4	2	وا	Mean Score	Comments
24 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4 4	ythema & Eschar					 ,,				•
72 4 4 4 4 4 4 4 4 4 7 7 7 2 4 4 3 4 3 4 4 4 4 7 3 7 2 4 3 3 4 3 3 4 3 3 4 3 3 4 3 3 4 3 3 4 3 3 4 4 3 3 3 4 4 3 3 3 4 4 3 3 3 3 4 4 3 3 3 4 4 3 3 3 4 4 4 4 3 3 3 3 4 4 4 4 4 3 3 3 3 4 4 4 4 4 5 2 4 4 4 5 3 3 3 3 4 4 4 4 4 5 3 3 3 3 4 4 4 4	Intact Skin	24	4	4	4	4	4	4	4.00	Category II compounds are
24 2 3 4 3 4 4 4 4 5	Intact Skin	72	4	4	4	4	4	4	4.00	compounds producing severe
72 4 3 4 3 4 4 4 3 7 72 4 3 4 3 4 3 4 3 4 3 4 3 4 3 4 3 4 3 4	Abraded Skin	24	~	3	4	٣	4	4	3.35	primary irritation of the
24 4 3 4 3 4 3 4 3 4 3 4 3 4 3 4 3 4 3 4	Abraded Skin	72	4	3	4	m	4	4	3.66	intact skin and of the skin
24 4 3 4 3 4 3 4 3 2 4 3 2 4 3 3 4 3 3 4 3 3 4 3 3 4 3 3 4 4 3 3 4 4 4 4 4 4 3 3 3 4 4 4 4 4 4 4 5 white the second secon			•	•	•	Sub.	toti	 급	14.99	surrounding an abrasion and, in
24 4 3 4 3 4 3 4 3 2 4 3 2 4 3 2 4 3 2 4 3 3 4 3 3 4 4 4 4	lema Formation									addition, producing necrosis and vesiculation.
72 4 3 4 3 4 3 2 4 3 72 0 4 3 3 4 3 4 4 4 4 4 4 4 4 4 4 4 4 4 4	Intact Skin	24	4	۳	4	3	4	<u>س</u>	3.50	
24 3 4 3 3 2 4 72 0 4 3 3 2 4 4 4 Total	Intact Skin	. 72	4	٣	4	٣	4	۴	3.50	
72 0 4 3 3 4 4 4 Subtotal Total	Abraded Skin	24	m	4	٣	٣	7	4	3.50	
	Abraded Skin	72	<u> </u>	4	<u></u>	 ;	4	4.	3.00	
						Tot	al al		13.50 28.49	
										. •

Skin reactions are evaluated using Draize scoring systems. Draize, J.H., Woodward, G. and Calvary, H.O., Methods for the Study of Irritation of Toxicity of Substances Applied Topically to the Skin and Murcous Membranes, J. Pharmacol and Exp Therap., 82: 777, 490, 944. 40 CFR 162

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APPENDIX K

COMPOUND: Package "A" Formulation of Disinfectant	"A" Formulation	n of	Dis	nfec	tant	.		USAE	USAEHA STUDY NO. 75-51-0195-84
PRIMARY SKIN EFFECTS NEW ZEALAND WHITE RABBITS	CTS	TOX	ICITY IV	ð	TOXICITY CATEGORY IV	* %		CONDITIONS Package A - 0.5g dry wh	CONDITIONS - Dry Package A - Single 24-hour application of 0.5g dry white powder per skin application
	Time of	_	Re	Response	şe şe				
	Observation	L	Rabi	Rabbit No.	٥٠				-
	Hours	-	2	3	4	5	9	Mean Score	Comments
Erythema & Eschar									
Intact Skin	24	0	0	0	0	0	٥	0	
Intact Skin	72	0	0	0	0	0	0	0	
Abraded Skin	24	0	0	0	0	0	0	0	Category IV compounds are
Abraded Skin	72	7	-1	0	0	0	0	0.50	
				_	į,	Subtotal	tal	0.50	mild or slight irritation at 72 hours.
Edema Formation									
Intact Skin	24	0	0	0	0	0	0	0	
Intact Skin	72	0	0	0	٥.	0	0	0	
Abraded Skin	24	0	0	0	0	0	0	0	
Abraded Skin	72	~	<u> </u>	0	<u> </u>	0	0	0.33	
					ΩĦ	Subtotal Total	tal	0.83	
					,				

Skin reactions are evaluated using Draize scoring systems. Draize, J.H., Woodward, G. and Calvary, H.O.), Methods for the Study of Irritation of Toxicity of Substances Applied Topically to the Skin and Mucous Membranes, J. Pharmacol and Exp Therap., 82: 777, 490, 944. +Lot 0611-1, 10/75, Chemical Compounding Corp., Riverhead, L.I., N.Y. * 40 CFR 162

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APPENDIX L

COMPOUND: Package	Package "A" Formulation of Disinfectant	on of	Dis	infe	ctan	44		USN	USAEHA STUDY NO. 75-51-0195-84
PRIMARY SKIN EFFECTS NEW ZEALAND WHITE RABBITS	crs	TOXI	CITY 11	TOXICITY CATEGORY*	EGOR	*		CONDITIONS Package A = 0.59 powder Water per sk	CONDITIONS - Wet paste Package A - Single 24-hour application of 0.59 powder mixed with? ml distilled water per skin application site
	Time of	L	Res	Response	0				
	Observation	L	Rabb	Rabbit No.	6				
	Hours	13	14	15	97		81	Mean Score	Comments
Erythema & Eschar									
Intact Skin	24	0	7	0	7	7	٦	1.0	Category II compounds are compounds
Intact Skin	72	7	7	7	7	7	7	2.0	producing moderate primary irri-
Abraded Skin	24	0	7	0	7	7	н	1.0	tation of the intact skin and of
Lbraded Skin	72	2	2	2	7	7	7	2.0	the skin surrounding an abrasion
			_	-	ns -	Subtotal	al	0.9	at 72 hours
Edema Formation									
Intact Skin	24	•	7	0	7	ਜ	н	1,0	
Intact Skin	72	_	0	ਜ	7	0	0	0.5	
Abraded Skin	24	0	7	0	<u>. </u>	7	7	1.0	
Abraded Skin	72	-	7	ਜ	ਜ <i>ਹੈ</i>	1 2 Subtota	٦ ,	E E	
					F F	Total		11.8	
				1	1				

Skin reactions are evaluated using Draize scoring systems. Draize, J.H., Woodward, G and Calvary, H.O., Methods for the Study of Irritation of Toxicity of Substances Applied Topically to the Skin and Mucous Membranse, J. Pharmacol and Exp Therap., 82: 777, 490, 944. Ltot 0611-1, 10/75, Chemical Compounding Corp., Riverhead, L.I., N.Y. *40 CFR 162

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APPENDIX M

COMPOUND:	Trichloromelamine	ine						USAEIIA STUDY NO.	UDY NO. 75-51-0195-84
ACUTE EYE EFFECTS NEW ZEALAND WHITE RARBITS	EFFECTS MILTE		TOX	ICIT	CAT I	TOXICITY CATEGORY*	٤	CONDITIONS - Unwas Trichloromelamine - application of 0.1 g dr one eye of each rabbit.	CONDITIONS - Unwashed eye test: Trichloromelamine - Single 24-hour application of 0.1 g dry white powder to one eye of each rabbit.
Time of				Š	Scores				
Reading				Rab	Rabbit No.	<u>.</u>			
Hrs-Days	Structure		1 2	3	4	2	9	Mean Score	Comments
	Cornea	9	4	- \$		6	6	43.3	Category I compounds are
24	Iris			_	5		2	9.9	compounds producing are
	Conjunctivae			- -		16	10	13.7	sive corneal opacity not
	Cornea		9	9	8	\$	ŝ	56.7	. coctatore within adys.
48	Iris	<u>유</u>		2		s	S	7.5	
	Conjunctiv		16	5 14	18		14	15.0	
	Cornea	9	 	09		9	40	60.09	
72	Iris	_	10	2			10	9.5	
	Conjunctiv	ae 16	20	0 - 14 	18	16	16	16.7	
	Cornea	8	 -	9			98	76.7	:
7-Days	Iris		10		20.		20	16.7	
	Conjunctivae	ae 24				24	24	22.3	
* 40 CFR 162	2				1				-

Draize, J.H., Woodward, G. and Calvary, H.O. Method for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes, J. Pharmacol and Exp Therap., 82: 377-393, 1944. The eye injury is evaluated according to a weighted scoring system used by Draize et.al.

War and the same

APPENDIX N

COMPOUND: Trichl	Trichloromelamine							USAEHA ST	USAEHA STUDY NO. 75-51-0195-84
ACUTE EYE EFFECTS HEW ZEALAND WHITE	EFFECTS D WHITE		TOXICITY CATEGORY*	711.	CATE	30 RX		CONDITIONS	S - Washed eye test
RABBITS				H	11			of 0.1 g dry w	of 0.1 g dry white powder to one eye of
Time of		igert		Sco	Scores		\prod	water for 1 mi	water for 1 minute 30 seconds after appli-
Hrs-Davs	Structure	<u> </u> -	- 1	Rabbit	اج ا			cation.	
	A TO TO THE	1	1	-	4	~	او	Mean Score	Comments
,	Cornea	-	10	0	-	0	•	1.7	Category II compounds are
87	Conjunctives	- E	ο <u>ά</u>	ې ه	0 6	٥٧	0 5	0.0	compounds producing mild
		-		3	3	2	F.4	7,.,	injury to the cornea, reversible within 7 days.
	Cornea		°	0	0	0	0	0.0	•
3	Iris		<u> </u>	0	0	0	0	0.0	•
	Conjunctivae		o 	0	0	0	0	0.0	
	Cornea	┼	0	0	0	0	0	0.0	
72	Iris	-	0	0	0	0	0	0.0	•,
	Conjunctivae		0	0	0	0	0	0.0	
	Cornea	 	0	0	0	0	0	0.0	•
7-Days	Iris	0	0	0	0	0	0	0.0	-
	Conjunctivae		0	0	0	0	0	0.0	
* 40 CFR 162				1	1	1	1		

The eye injury is evaluated according to a weighted scoring system used by Draire et.al.
Draire, J.H., Woodward, G. and Calvary, H.O. Method for the Study of Irritation and Toxicity
of Substances Applied Topically to the Skin and Mucous Membranes, J. Pharmacol and Exp Therap.,
82: 377-390, 1944.

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APPENDIX 0

CONPOUND:	Potassium Iodide							USAEHA STI	USAEHA STUDY NO. 75-51-0195-84
ACUTE EYE EFFECTS NEW ZEALAND WHITE	EFFECTS D WHITE	•	TOXICITY CATEGORY*	i Y	ATEG	ORX*	_	CONDITION	CONDITIONS - Unwashed Eye Test Potassium Iodide - Single 24-hour
RABBITS				111				application crystalline	application of 0.1 g of dry white crystalline compound to one eye of
Time of				Scores	es		r	each rabbit.	Ť.
Reading			2	Rabbit No.	2			•	
Hrs-Days	Structure	1	2	3	4	2	9	Mean Score	Comments
	Cornea		0			0	0	0.0	Category III compounds are
24	Iris		0				0	0.0	compounds producing no
	Conjunctivae	10	4	10	10	12	12	7.6	corneal opacity, irritation reversible within 7 days.
	Cornea	 -	o.	0	0	0	0	0.0	
48	Iris	-	0	0	•	0	0	0.0	
•	Conjunctivae	ot	0	10	12	4	w	5.3	
	Cornea	 	0	0	0	0	0	0.0	
22	Iris	0 0	00	0 9	0 8	0 7	0 4	0.0	
		-	'	·	-				
	Cornea		0	0	0	•	0	0.0	
7-Days	Iris	0	0	0	0	0	0	0.0	
نبيد نست	Conjunctivae		0	0	0	0	0	0.0	
* 40 CFR 162	2				1	1	1		

The eye injury is evaluated according to a weighted scoring system used by Draize et.al.
Draize, J.H., Woodward, G. and Calvary, H.O. Method for the Study of Irritation and Toxicity
of Substances Applied Topically to the Skin and Mucous Membranes, J. Pharmacol and Exp Therap.,
82: 377-390, 1944.

APPENDIX P

CONTROLID: F	Compension Forassium Iodide							USAEHA STU	USAEHA STUDY NO. 75-51-0195-84
ACUTE EYE EFFECTS	EFFECTS WHITE		TOXICITY CATEGORY*	ITY (CATEC	ORY '		CONDITIONS - Potassium Iod	CONDITIONS - Washed eye test . Potassium Iodide (KI) - Single appli-
RABBITS				Ħ				cation of 0.1	cation of 0.1 g dry white crystalline compound to one eye of each rabbit. Eye
Time of		_		Scores	es			Washed out wit	17
Reading			æ	Rabbit No.	S S			30 secs. after	application.
Hrs-Days	Structure	1	2	3	4	5	9	Mean Score	Comments
	Cornea		40	0	0	0	0	6.7	Category II compounds are
24	Iris	0	9	0	0	0	0	1.7	compounds producing mild
	Conjunctivae		81	77	7	9	77	11.2	injury to the cornea; reversible within 7 days.
·	Cornea		0	٥	0	0	0	0.0	•
84	Iris	<u> </u>	0	0	0	0	0	0.0	
	Conjunctivae		٠	0	0	0	0	2.0	
	Cornea		0	0	0	0	0	0.0	
72	Iris		0	0	0	0	0	0.0	
	Conjunctiva	~	~	0	0	0	0	0.7	
	Cornea	 	0	0	0	0	0	0.0	•
7-Days	Iris	<u> </u>	<u> </u>	0	0	0	0	0.0	
	Conjunctiva		<u> </u>	0	0	0	0	0.0	
• 40 CFR 162	2				1				

The eye injury is evaluated according to a weighted scoring system used by Draize et.al. Draize, J.H., Woodward, G. and Calvary, H.O. Method for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes, J. Pharmacol and Exp Therap., 82: 377-390, 1944.

APPENDIX Q

CONFOUNDS	Complete disinfectant mixture with KI.	tant m	ixtur	e wir	45 12	ن ا		USAEHA STUDY NO.	IDY NO. 75-51-0195-84
ACUTE EYE EFFECTS NEW ZEALAND WHITE	EFFECTS D WHITE		TOXICITY CATEGORY*	7.1.1	ATE	DRY.		Disinfectant nof 0.1 ml aque	CONDITIONS - Unwashed eye test. Disinfectant mixture - Single application of 0.1 ml aqueous disinfectant solution
RABBITS			1	IV	1			to one eye of	to one eye of each rabbit. Dry disinfectant mixture diluted with water to "use"
Time of				Scores	es			formulation (formulation (1.7 mg mixture/ml water).
Reading			2	Rabbit No.	Š				
Hrs-Days	Structure	-	7	3	4	5	و	Mean Score	Comments
	Cornea	•	0	0	0	0	0	0.0	Category IV compounds are
24	Iris	0	•	0	0	0	0	0.0	compounds producing no
	Conjunctivae	<u> </u>	0	0	0	0	0	0.0	irritation to the eye.
	e de la Co	-	0	0	0	6	0	0.0	,
48	Iris	-	0	0	0	0	0	0.0	
	Conjunctivae		Ο.	0	0.	0	0	0.0	
	Cornea	-	0	0	0	0	0	0.0	
22	Iris	<u> </u>	0	0	0	0	0	0.0	
	Conjunctivae		0	0	0	0	0	0.0	
	Cornea	0	0	0	0	0	0	0.0	
7-Days	Iris	٥	0	0	0	0	0	0.0	
	Conjunctivae		•	0	0	0	0	0.0	
. 40 CFR 162	2				1				

The eye injury is evaluated according to a weighted scoring system used by Draize et.al. Draize, J.H., Woodward, G. and Calvary, H.O. Method for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes, J. Pharmacol and Exp Therap., 82: 377-390, 1944.

The Marie Carl

Q-1

APPENDIX R

CONTROL ID:	Aqueous (use) solution complete disinfectant mixture with KI.	lution ture wi	compl th KI	ete				USAEHA STU	USAEHA STUDY NO. 75-51-0195-84
ACUTE EYE EFFECTS	EFFECTS		TOXICITY CATEGORY*	ITY (CATE	30RY		CONDITIONS - W	CONDITIONS - Washed eye test. Disinfectant mixture - Single application
RABBITS	- white			ΛI				to one eye of	of U.1 ml aqueous disinfectant solution to one eye of each rabbit. Dry disinfec-
				I				tant mixture d	tant mixture diluted with water to "use"
Time of		_		Scores	res			formulation (formulation (1.7mg mixture/ml water).
Reading	•	_		Rabbit No.	r No		-		
Hrs-Days	Structure	-	7	~	4	2	٥	Mean Score	Comments
	Cornea		0	0	0	0	0	0.0	Category IV compounds are
24	Iris	-	0	0	0	0	0	0.0	compounds producing no
	Conjunctivae		<u> </u>	0	0	0	0	0.0	irritation to the eye.
		┼	c	C	c	6	c	0.0	
84	Iris	_	· o	0	0	0	0	0.0	
	Conjunctivae		<u> </u>	•	0	0	0	0.0	
	Cornea	┼	0	0	0	0	0	0.0	
22	Iris	-	<u> </u>	00	0 0	0 0	0 0	0.0	
	Conjunctiva		,	>	>	,	,		
	Cornea		0	0	0	0	0	0.0	•
7-Days	Iris	0	° —	0	0	0	0	0.0	
	Conjunctiva		<u> </u>	0	0	0	0	0.0	
4 40 CFR 162	2				1				

The eye injury is evaluated according to a weighted scoring system used by Draize et.al. Draize, J.H., Woodward, G. and Calvary, H.O. Method for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes, J. Pharmacol and Exp Therap., 82: 377-390, 1944.

APPENDIX S

COMPOUND: Disinfe	Disinfectant mixture, complete with KI, Dry	ture, o	omple	te wi	th K	I, D	7	USAEHA STIIDY NO	INV NO 75-61 0105 04
ACUTE EYE EFFECTS	EFFECTS		TOXIC	TOXICITY CATEGORY*	CATE	GORY		CONDITIONS	CONDITIONS - Unwashed eye test.
RABBITS	ALTUM C			H				application of	Disinfectant mixture - Single 24-hour application of 0.1 g brownish dry, com-
Tine of		F		Sco	Scores			Proce mixeure	Fred mixeure to one eye or each rabbit.
Reading				Rabbit No.	t R		T		
Hrs-Days	Structure	-	2	13	4	2	9	Mean Score	
	400	9	7	9	3	3	3	П	RT (Janaaro)
24	Trie	3 5		3 5	2 5	2 5	2 5		Category I compounds are
	Conjunctivae	16	14	16	16	2 7	91	15.3	compounds producing corro- sive corneal opacity not
		+	4						reversible within 7 days.
	Cornea		40	9	9	09	9	56.7	
48	Iris		2	2	10	S	2	7.6	•
	Conjunctivae	16	2	14	16	16	16	14.7	
		+	\perp		1	1	T		
-	Cornea	9	20	40	9	9	9	50.0	
2/	Iris	70	5	. 5	10	2	50 1	6.7	
	Conjunctivae		5 1	77	9	9	٥	12.7	
	Cornea	28	2	2	2	2	200	20.0	
7-Days	Iris	0	0	0	0		0	0.0	
	Conjunctivae		•	ဖ	9	9	9	6.0	
. 40 CFR 162		1			1	1	7		

The cye injury is evaluated according to a weighted scoring system used by Draize et.al.
Draize, J.H., Woodward, G. and Calvary, H.O. Method fcr the Study of Irritation and Toxicity
of Substances Applied Topically to the Skin and Mucous Membranes, J. Pharmacol and Exp Therap.,
82: 377-390, 1944.

APPENDIX T

GKTOGEKOD	CO:SOL:1D: Disinfectant mixture complete with KI, Dry	e com	plete	with	KI,	a d		USAEHA STI	USAEHA STUDY NO. 75-51-0195-84
ACUTE EYE EFFECTS	EFFECTS WHITE		TOXICITY CATEGORY*	ITY (ATEC	XORY.		Disinfectant nof 0.1 g brown	CONDITIONS - Washed eye test Disinfectant mixture - Single application of 0.1 g brownish, dry complete mixture
RABBITS				II	ш			to one eye of out with disti	to one eye of each rabbit. Eye washed out with distilled water for 1 minute
Time of				Scores	es			30 seconds at	30 seconds after application.
Reading			K	Rabbit No	2			•	
Hrs-Days	Structure	_	2	3	4	5	٥	Mean Score	Comments
	Cornea	0	40	09	09	30	45	39.1	Category II compounds are
24	Iris	S	2	2	10	S	21	7.6	compounds that produce
	Conjunctivae	16	18	18	18	18	18	17.71	corneal opacity, reversible within 7 days.
	Cornea	0	10	20	2	0	2	8.3	
48	Iris	0	2	S	0	0	0	1.7	
	Conjunctivae	o <u>.</u>	ន	10	12	0	12	7.0	
	Cornea	0	S	15	5	0	5	5.0	
72	Iris	00	5 2	0 4	0 60	00	0 9	0.8 3.7	
		+			十				·.
	Cornea		•	0	0	0	0	0.0	
7-Days	Iris	<u> </u>	• 	0	0	0	0	0.0	
	Conjunctivae		•	0	0	0	0	0.0	
* 40 CFR 162	2	-			1				

The eye injury is evaluated according to a weighted scoring system used by Draize et.al. Draize, J.H., Woodward, G. and Calvary, H.O. Method for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Mambranes, J. Pharmacol and Exp Therap., 82: 377-390, 1944.

APPENDIX U

NEW ZEALAND WHITE	CONPOUND:	Package "A" ** Formulation of Disinfectant	ulation	of I	isin	fect	ant	ł	USAEHA ȘT	USAEHA STUDY NO. 75-51-0195-84
Structure	ACUTE EYE 1	EFFECTS	••	OXIC	ITY (:ATE	30RY 1		CONDITIONS Package A	2 Unwashed eye test
Structure	RABBITS	MALIE			H				Single 24	-hour application of 0.1g du der to one eye of each rabbi
Structure	Time of		-		Scol	es				
Cornea 1 2 3 4 5 6 Mean Score Comments Cornea 20 0 80 0 30 35.0 Category I compounds Iris 5 10 10 5 5 10 10 5 6.7 compounds producing Cornea 18 18 18 18 18 18 10 10 5 6.7 compounds producing Cornea 20 5 10 10 5 5 6.7 compounds producing Iris 16	Reading		L	۳	abbit	8		Γ		
Cornea 20 0 80 80 0 35.0 Category I compounds producing injury to the corner conjunctivae. Conjunctivae 18	Hrs-Days	Structure		7	- -	4	2	9	Mean Score	Comments
Cornea Conjunctivae 18 18 18 18 18 18 18 1		Cornea	20	0	80	90	0	30	35.0	Category I compounds are
Conjunctivae 18 16 16 14 20 16 14 20 16 14 20 16 14 20 16 14 16 14 16 14 16 14 16 16 16 16 16 16 16 16 16 16 16 16 16 16 17 3 Cornea 5 0 0 5 0 5 17 3 Cornea 5 5 60 5 0 5 13 3 Days 1ris 5 0 0 0 0 0 0 0 0 0 0	24	Iris	S	S	10	10	2	2	6.7	compounds producing severe
Cornea 20 5 80 20 5 20 25.0 Iris 5 10 10 0 5 5.8 5.8 Conjunctivae 16 16 14 20 16 14 16.0 Cornea 20 10 80 20 0 20 25.0 Conjunctivae 20 18 18 18 12 18 17.3 Days Iris 5 60 5 0 5 13.3 Conjunctivae 5 5 60 5 0 0 0 Conjunctivae 16 16 14 16 8 18 14.7		Conjunctivae		18	18	18	18	18	18.0	injury to the cornea and conjunctiva. Corneal
Cornea 20 5 80 20 5 20 25.0 Conjunctivae 16 16 14 20 16 14 16.0 Cornea 20 10 80 20 0 20 25.0 Iris 5 0 0 5 0 5 22.5 Conjunctivae 20 18 18 18 12 18 17.3 Cornea 5 5 60 5 0 6 00.8 Conjunctivae 16 16 14 16 8 18 18 14.7			-	,	1	1	,	1		opacity persistent at
Cornea 20 10 10 0 20 14 15 15 15 15 15 15 15 15 15 15 15 15 15	48	Trie	07	n 4	2 5	2 5	n c	3 4	0.07	
Cornea 20 10 80 20 0 20 Iris 5 0 5 0 5 0 5 Conjunctivae 20 18 18 18 12 18 Cornea 5 5 60 5 0 5 Conjunctivae 16 16 14 16 8 18	2	Conjunctivae		9	14		9	14	16.0	
Cornea 20 10 80 20 0 20 Iris 5 0 5 0 5 0 5 Conjunctivae 20 18 18 18 12 18 Cornea 5 5 60 5 0 5 Cornea 5 0 0 0 0 0 Conjunctivae 16 16 14 16 8 18				2			}			-
Iris Conjunctivae 5 0 5 0 5 5 5 5 5 5		Cornea	20	10	80	20	0	20	25.0	
Conjunctivae 20 18 18 18 18 18 18 18 18 18 18 Cornea 5 5 60 5 0 5 0 5 0	72	Iris	2	0	0	S	0	S	22.5	
Cornea 5 5 60 5 0 5 Iris 5 0 0 0 0 0 Conjunctivae 16 16 14 16 8 18		Conjunctivae		18		18	12	18	17.3	
Iris 5 0 0 0 0 0 0 Conjunctivae 16 16 14 16 8 18		Cornea	2	5		2	0	5	13.3	
unctivae 16 16 14 16 8 18	7-Days	Iris	Ŋ	0		0	0	0	0.8	
		Conjunctivae		91		91	ω	18	14.7	

of Substances Applied Topically to the Skin and Mucous Membranes, J. Pharmacol and Exp Therap., The eye injury is evaluated according to a weighted scoring system used by Draize et.al. Draize, J.H., Woodward, G. and Calvary, H.O. Method for the Study of Irritation and Toxicity 82: 377-390, 1944. Lot No. 0611-1, 10/75 Chemical Compounding Corp., Riverhead, L.I., N.Y.

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APPENDIX V

COMPOUND:	Package "A" Formulation of Disinfectant	ation	of Di	sinf	ectan	ايد ا		USAEHA ST	USAEHA STUDY NO.75-51-0195-84
ACUTE EYE EFFECTS NEW ZEALAND WHITE RABBITS	EFFECTS D WHITE	-	TOXICITY CATEGORY*	ITY (ATEG	ORY *		CONDITIONS - Was Package "A" - Si 0.1g dry white p of each rabbit.	CONDITIONS - Washed eye test Package "A" - Single application of 0.19 dry white powder to one eye of each rabbit. Eye washed out with
Time of		-		Scores	es		-	distilled	-
Reading		L	۳	Rabbit No.	ş		Γ	seconds a	seconds after application.
Hrs-Days	Structure	13	14	15	16 17	7	118	Mean Score	Comments
	Cornea		0		10	0	0	4.2	
24	Iris	-	0	5	S.		0	2.5	Category II compounds are
	Conjunctivae	22	14	18	22 2	- (4	22	19.7	compounds producing moderate
		-	L		-	T	+		addition, producing some
·	Cornea		0	0	S		•	0.8	injury to the conjunctiva.
48	Iris	<u> </u>	0	0			<u>ဂ</u> ၀၀	0.0	Corneal opacity reversible
	Conjunctivae		9	14	14 1	12 1	10	10.7	within 7 days, irritation
					1	1	-		persisting for 7 days.
	Cornea		0	0	0	0	0	5.0	
72	Iris		0	0	0	0	•	0.0	
	Conjunctivae	10	4	14	60	7	12	. 3°.	
		-	0	ſ	-	1	-		•
	cornea.	_	•		5 6				
/-Days	Iris		-	5 (5 .		- -	0.0	
	Conjunctivae	4	~	9	4	<u> </u>	 co	4.0	
* 40 CFR 162					1	1	1		

The eye injury is evaluated according to a weighted scoring system used by Draize et.al.

Draize, J.H., Woodward, G. and Calvary, H.O. Method for the Study of Irritation and Toxicity

of Substances Applied Topically to the Skin and Mucous Membranes, J. Pharmacol and Exp Therap.,

82: 377-390, 1944.

Lot No. 0611-1, 10/75

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APPENDIX W

COMPOUND:	Trichloromelamine	comelam	ine							ISAEH	USAEHA STUDY NO. 75-51-0195-84	10. 75	-51-01	95-84			
			LDEA	1 3	690 mg/kg	63			1	95% C.L.	L. 560 -		870 mg/kg	5			
ACUTE ORAL LDSO	1 LDS0		Slope	pe 6.02	2				01	S.E.	1.70			1		•	
SPRAGUE-DAWLEY, WIST	TS AWLEY, WI	STAR	Con	Conditions Administered	Adm	inist	ered	되	dist	111ec	distilled water a	as 50%		solutions	500 mg/ml	ng/m1	
	. [- 1	- 1											1	- 1
			Onset of	of signs	- 1	(S), mc	mortality	7	E	Ī	Mort	Mean	:	real	ł	X WCS	76)
Dosage	Conc		Hours	rs		ŀ	-		- 1-	1	Cumula-	Body	الد		Days	5	1
mg/kg		9-4	4-12	12-24	7		4 5	9		8-14	tive	Init	Fin	301	200	241	355
503	20										9/0	±17	±26	+ + +	+14	±15	126
							\vdash			T		207	264	204	206	244	264
631	20		83	M3							3/6	‡16	±20	8+	‡ 4	+ 5	±20
							-					199	267	190	907	246	267
795	S	98	S 6	M4							4/6	+19	±13	±15	114	‡16	±13
			98	98			\vdash	L	-			195	258	133	881	1531	258
1000	20	Œ	Œ	75							4/6	8 +	±25	123	₹30	±23	±25
					_		-		-			192					
1269	22	W e		 							9/9	‡15		-	å	•	•
					L		-	L	-			881					
1585	20	-	S5	Z.	M						9/9	+17	,	-	1	1	٠
Control			_				\vdash	_				184	250	186	195	230	250
ml/wate	-										9/0	+ 9	+ 4	±3	16	111	14
						T	╁	1									
							ᅱ	_	_		7						
Stans of	Signs of Intexication Lethardy qasping were seen in 12 hours, signs at 24 hours following 1000 mg/kg	tion L	etharg	/ qaspir	IG WE	re 8	een	i E	2 50 50	urs,	signs at	24 h	ours f	ollo	ring 1	000	2/kg
lethargy	lethargy ruffled pelt red exudate around eyes.	pelt r	ed exuc	date arc	punc	еуев											٠
Gross Autopsy:	topsy: N	No chan	ges in	changes in decedents or survivors.	its c	ir su	rviv	ors.		gros	No gross compound related changes seen at	nd re	lated	chang	jes se	en at	
necropsy.																	

Probit analysis by the method of Bliss.
 CFR 162
 Toxicity Category III

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APPENDIX X

COMPOUND:	Potassium		Iodide (KI)							USAEH	USAEHA STUDY NO.	1	5-51-(75-51-0195-84	4		
			LD50*		4800 mg/kg	/kg				951 C.L.	.L. 4200	- 550	5500 mg/kg	51			
ACUTE ORAL LDSO	L LDSO		Slope	pe 15.0	0					S.E.	5.17			. 1			
SPRAGUE-DAWLEY, WIS	AWLEY, WI	STAR	Š	Conditions Administered in	Adm	inis	tere	d in		tille	distilled water	as 50%	water		ution	solution (500 mg/	mg/
					kg/	l ml	l wa	water)			,						
			Onset of	1 1	signs (s), mortality (m)	Ě,	orta	lity	Œ		Mort	Mean		Mea	n Bod	Mean Body Wts.	(9)
Dosage	Conc		Hours	ırs			Ω	Days			Cumula-	Body	¥t.		Days	9	
m3/1:9		0-4	4-12	12-24	2	3	4 5	9	7	8-14	tive	Init	Fin	1	3	7 .	14
								_	_			185	245	182		198	245
2510	20						_		_		0/6	+7	±14	± 2	í	∓8	+14
							_					161	260	161		202	260
3160	50							_			9/0	± 2	∓6	+7	ı	±14	+ 6
							_	_				196	282	181		180	282
3980	50		S 2	MI		_					1/6	8+1	±18	±13	•	±21	±18
							_	_	 			201	244	180		214	244
5010	50		S2	M2	Œ		-				3/6	1 0	±14	+13	-	+20	±14
					_		-					191					
6310	50	98		M6				_	_		9/9	±11	1	ı	ı	1	ı
Control							\vdash	_				192	277	201		250	277
l ml water						- -					9/0	9 +	4 6	9∓	1	+8	1
									_								
							+	4	1	1				1		1	
						†	+	1	1						T	1	T
						-	-			-							
Signs of intoxication:	intoxica	rion:	Major	e jane	97.0	a tax	, a	7	460	8	Major eigns were staxis and weakness and death over first 24 hours	3010	407	24 12		٢	
signs after 24 hours.	er 24 ho	urs.	- A	511645	1		5 5 1	2	200	ל מ מ	וות מבשרוו	1940	76777			2	
Gross Autopsy:	opsy: No	o chang	jes in	changes in decedents or survivors.	ıts o	r su	rviv	ors.		gros	No gross compound related changes seen at	d rel	ated	chang	98 89	en at	
10.30						l		1	1					l			1

* Probit analysis by the method of Bliss. 40 CFR 162 Toxicity Category III

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APPENDIX Y

CC:BOR:D:	}	Disinfectant mixture	míxtu	re					USAEIU	USAEIIA STUDY 140.		5-51-	75-51-0195-84	8		
			LDS	LD50>22 mL/kg or 36 mg/kg	/kg o	36	g/kg		954 C.L.	.t.				ŀ		
ACUTE ORAL LDSO	L LDSO		Slope	pe	per	rat			ສຸ				1			
SPRAGUE-DAWLEY, WIST	NAMEY, W	STAR	Con	Conditions		infect	antı	mixtu	ire foi	Disinfectant mixture formulated 1.7 mg/ml	1.7 m	3/m1			•	
				•		Dosages .005, .01,	005,	.01,	.02,	.03 ml/gm body weight	poq m	y weic	tht			
			Onset of	of signs	s (s),	, mor	mortality	y (m)		Mort	Hean		Nean		Body Wts.	(6)
Dosage	Conc		· Hours	rs			Days			Cumula-	Body	Wt.		Days	S	
mT/dm	9	0-4	4-12	12-24	2	3 4	5 6	7	8-14	tive	Init	Fin	1	3	7	14
	1										185	280	195	205	255	280
.005	.17					1	1	-		970	±13	±18	112	-1	115	±18
7	5										187	288	238	245	250	288
10.	77.					-		 		9/0	+20	±25	±19	111	116	+25
											180	263	223	230	240	263
.02	.17							4		9/0	±17	±21	±14	6 +	77	121
					_						191	271		250	250	271
.03	.17					\dashv		-		9/0	±14	+17	121	117	±18	7
Control	:				-						187	280		249	259	280
. U1 m1)Ţ:					4		-		9/0	±23	±30	+20	121	±23	430
water/gm body wt.																
						-		-								
						4		1						1	1	
									-							
Signs of intoxication: Gross Autopsy: No chan	l ă	tion: chang	No signs jes in su	ation: No signs No changes in survivors.	ł	lo gre	6	noduc	nd re]	No gross compound related changes seen at necropsy.	nges (seen a	st nec	ropsy.		·

40 CFR 162 Toxicity Category IV

APPENDIX Z

CCMPOUND: Disinfectant mixture, complete with KI, wet	Disinfect	tant mi	xture,	comple	te wi	늄	Ä,	Wet		USAEH	USAEHA STUDY NO.	1	-21-0	75-51-0195-84	4	'	
			LD _{SO} *		2400 mg/kg	Kg	1			958 C	C.L. 2000	- 2800	2800 mg/kg	넑			
ACUTE OPAL LDSO	L LDSO		Slope	pe 7.56	56	Ì	1			S.E. 2.04	2.04			1		_	
SPRAGUE-DAMLEY, WIST	AWLEY, WI	STAR	Con	ditions	Adi	nini	ster	ed i	r di	still	Conditions Administered in distilled water as		Wate	er slu	50% water slurry (500 mg/ml	(500 m	(Lm/6)
			Onset of	of signs	s (s),		mortality (m)	lity	E		Mort	Mean		Pea	Hean Body Wts	y Wts.	(6)
Dosage	Conc		Hours				Δ	Days			Cumula-	Body	Wt.		Days	s	
mg/kg	1	0-4	4-12	12-24	7	3	4 5	9	7	8-14	tive	Init	Fin	1	,	12	14
						-	-	_				183	251	174	202	245	251
1269	20		S6						Z.		1/6	9∓	±11	±27	± 8	±11	±11
	-						-	_	_			189	232	179	196	228	232
1585	50		S6								9/0	+11	±18	±13	±14	±18	±18
				•				_			2, -	198	215	991	182	212	215
2000	50		S6	25	MI			_			1/6	+10	±24	±25	±23	±21	±24
			98	25			-	-				506	249	201	217	243	249
2510	20		Ml	MJ			_				5/6	1 12	+20	±22	+22	±17	±20
			98	25			_	_				202					
3160	20		M3	Md				_			9/9	8 +				_	
				-			-	\vdash	_			717					
3980	20	W	MS				-				9/9	841					
Control			ļ 				┞	L				177	254	199	216	250	254
l ml water								_			9/0	+ 8	±10	+ 9	49	8+1	±10
							+	+]								
										•				·			
2000	7						1	1 3] }	tatheren again to the 12 hours and the second of the 12 hours	7000		֓֞֜֜֜֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓		١,	
Gross Autopeve	Signs of incoxication:	cton:		on: Lethargy gasping Within 12 not change in decedents or survivors	to at	בור	1 2	1 d	N N	2 2 2 2 2 2	red exidate alound eyes at 14 Houss	A rel	eyea atod	י אר פרלי המפלי		. מ . ב . ב	
מפנים מו				10000) 9	,	, , ,	5		2 } * }		1	; ; ;)))		•
necropsy.																	
																	_

*Probit analysis by the method of Bliss. 40 CFR 162 Toxicity Category III

Z-1

APPENDIX AA

COMPOUND: Package	Package	'A"*" A"	ormule	A*** Formulation of Disinfectant	Dis	Infec	tant		ğ	SAEHA	USAEHA STUDY NO.	1 1	75-51-0195-84	0195-8	¥		
			LDS	LD ₅₀ * 3000 mg/kg	Du O	189	j		<u></u>	 5€	95% C.L. 2500-3600 mg/kg	3600	mg/kg	1			
ACUTE ORAL LDSO	r rb50		510	Slope 7.23	5		1		S	E. of	S.E. of Slope: 1.82	1.8		1			
SPRAGUE-DAWLEY,		WISTAR	CO	ditions	Adm	inist	ered	4	dist	111ed	Conditions Administered in distilled water as	18 30	30% solutions (300 mg/ml)	tions	(300	m/bm	<u></u>
			Onset of	of signs		(s), mortality (m)	rtal	İty	Œ	[=	Mort	Mean		Mean		Body Wts.	(g)
Dosade	Suc		Hours	rs			Days	Ę.			Cumula-	Body	Body Wt.			S	1
260200	2	0-4	4-12	12-24	2	3 4	5	9	7 8	8-14	tive	Init	Fin	1	3	7	14
					T	-	_		-	-		183	265	193	196	215	265
1590	30					Sl					9/0	9+	17	±4	±4	±14	+7
									-	-	,,,	184	277	102	204	242	277
2000	30					25		 로			1/6	+5	+9	9+	+7	+10	6+
						\vdash		9	-	-	, , ,	184	397	184	187	233	266
2510	30						<u></u>	 Z			٥/٥	+2	+9	9+	+8	+12	6+
						-	_		-		,,,	195	366	184	202	218	566
3060	30										4/1	+11	+35	+10	+19	+25	+35
				!	Ā	\vdash	_		-		2/2	193	263	176	204	218	263
3980	30			Ē	Sl				_	_	0/0	+16	•	+23	•	-	-
];	;	Г	. 3	_		-		2/ 2	181	ı	158	1	1	ı
5010	30		9s	£	Į	Į.	-		_		9/9	+7	•	+19	,	-	-
6310	30	98	 	W6							9/9	186	ı	ı	1	1	ı
Control						+	-		\vdash	T	3, 6	184	264	199	205	221	264
1ml/water	•					-	\dashv		\dashv		٥/٥	7	-112	Φ	8+	+12	+12
							 :										
Sions of intoxication:	intoxica	t ion:	Conve	Convulsions, listlessness, shallow breathing, red discharge from nose, ataxia	list	lessi	ness,	sha	1119	, bre	thing,	red d	ischar	ge fr	of mo	3e, a	taxia

Signs of intoxication: Convulsions, listlessness, shallow breathing, red discharge from mose, an Gross Autopsy; No changes in decedents or survivors. No gross compound related changes seen at necropsy.

*Probit analysis by the method of Bliss.

40 CFR 162 - Toxicity Category III *** Lot 0611-1, 10/75, Chemical Compounding Corp., Riverhead, L.I., N.Y.

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APPENDIX BB

COMPOUND:	COMPOUND: Trichloromelami	omelam	ine**							USAEHA	USAEHA STUDY NO.	•	75-51-0195-84	9-84				
			LD50*	1	10.0 g/kg	5	1		Ì	95% C.L.	L. 8.4	8.4 - 11.8 g/kg)kg				•	
ACUTE DERMAL LDSO	WAL LDSO		Slope	t	1.34	l	1			S.E. 1.83	1.83							
MALE	MALE RABBITS		O	Conditions	Adı	inis	ter	Sq. as	dr	Administered as dry powder.		Subject skin and test compound moistened	and I	test	Comp	und	moist	ene
NEW ZEALAND WRITE	STILM ON				3	विस्	ysi	with physiological	cal	salin	ior	to subject exposure	ex ex	posure				1
			Onset of	of signs		m,	orta	mortality (m)	Œ		Mort	Mean	_	Mean Body Wts.	Apo		(kg)	1
Dosade	Conc		Hours				Δ	Days			Cumula-	Body Wt.	<u> </u> :		2			1
g/kg		0-4	4-12	12-24	2	3	4 5	9	17	8-14	tive	Init	_		4	7	5	
1							_			S1	0/4	3.73 3.	3.51 3.6	3.68 3.51		4.45 2.45 4.45 4.45	3. 5. +	
)							1	1	1			Ŧ	200	3 46 3 30	4	3000	36 2	T
3.2					SI	포					1/4	• ••	+.65 + .	+.28 ±.43			±.65	
					\downarrow		\dagger	+	1			ſ	3.63 3.	3.73 3.4	14 3	3.27 3	3.63	
10.0						<u></u>	S2			¥2	2/4		±.18 ±.	4.32 4.24		±.26 ±	₹.18	
		Ì			1	1	\dagger	+	1			3.80 3.87	_	3.78 3.80	 -	3.833	3.87	
grapped Only	110													4.38 4.39		±.36 ±	±.39	1
					1		╁	1					-	-	-	-		== :
						-			_				-	-	\dashv	-	7	
			_	_	_		-	-					 					
					_	1	+	+					+	+	+	- -	\dagger	
																	-	#7 1.
							+	-					-	-	-	-	\vdash	
·					4		7	-	\Box				+	+	+	\dagger	1	1
										-								
10000	Signature of intoxication.	غ ا	Nagal					lled	ۻ ۻ	King	discharge uncontrolled jerking movements,	, skin areas necrotic with edema	reas	necro	tio w	ith	dema	١.
fast sha	fast shallow breathing.	hing.) 		!	! !	,	•						•		
Gross autopsy:	topsy: No	chan	ges in	organs	of d	eced	ents	or	surv	'ivòrs'	No changes in organs of decedents or survivors, skin application sites evidence of eschar.	plicatio	n sit	es ev	idenc	e of	esch	ar.

* Probit analysis by the method of Bliss. ** Lot 409R Union Comp Corp., Wayne, N.J. 40 CFR 162 Toxicity Category III

APPENDIX CC

COMPOUND: Trichloromelamine	Trichlor	omelan	nine							JSAEH	PROJEC	USAEHA PROJECT NO. 75-51-0195-84	1-01	95-84				
			10504	1 '	2200 mg/kg	kg	,		6	58 C.	1200-	95% C.L 1200-3900 mg/kg						,
ACUTE DEPINAL LOSO	MAL LOSO		Slope	e 4.24	4		1		S	S.E.	1.94							
HEW ZEALAND WHITE	ABBITS ND WHITE		Con	litions	Adm	inist	ered	in	dist	tille	Conditions Administered in distilled water	at concentrations of 90 mg/mL	trat	ions	of 3	Date 0	星	1
			Onset of	of signs	s (s),	J.	mortality	ty	Œ		Hort	Mean	H	Hean	Body	Body Wts. (kg)	(kg)	
Dosage	Conc		Hours				Days	ຄ		 	Cumula-	Body Wt.	ال		Davs			
64/5vm	•	0-4	4-12	12-24	2	9	5	9	7 8	8-14	tive	Init Fin	ı.	1 1	2	5	7	14
						-			-			3.90 3.35		3.66	_	-	3.50	3.35
450	6					_			_		0/4	1.16 1.31	اند	24	_		±.32	±.31
						-			-			3.81 3.29		3.68			3.41	3.24
900	6								_		0/4	±, 59 ±.5	53 #.	57			1.47	±.52
						-	_		-			3.78 3.18		3.55			3.23	3.18
3 600	6				H	111		_		۰	2/4	4.16 4.1	+	÷.09	1	7	7	±. 11
						-	_		-			3.54 2.4	5	10			2.68	2.47,
3600	5				E	HI		<u></u>	<u> </u>		3/4	+.56 -	.	.62		7	±.18	
Control			_			-	-		-			2.64 2.62		2.44 2.	2.55 2.75	.75	2.59 2.6	2.62
1 ml water,	/-										0/4	±.05 ±.14		4.11 4.	±.09 ±	4.12	4.19	77
63																		
100						1 3											3	
Severe De	severe orimary irritation	itati	on at 7 days	davs.	1 d	110		ָ ט ט	9 401	7	* TDO	shin ilitarion at all conays levels of nous alter application progressing to	9		1	1000	? ?	
Gross Autopsy:	opsy: No	chan	ges in c	rgans	skin	app	Licat	ton	61.t	88 eV	idence c	No changes in organs, skin application sites evidence of eschar.	_					
		1														1		7

Probit analysis by the method Bliss.
 CFR 162
 Toxicity Category III

APPENDIX DD

COMPOUND:	Package	"B" F	ormula	formulation of Disinfectant (K1)	Disir	fect	ant	(K1)	USAEH	USAEHA STUDY NO.	ł	75-51-0195-84			
			es i	LD50* 3.69 9/kg	QB 69	9	1		958 C	954 C.L. 3.03 -	- 6.71 g/kg	53			
ACUTE DERMAL LD50	WL LD50		Slc	Slope 10.97	.97		١		S.B.	128		j		•	
NEW ZEALAND WHITE	ABBITS AD WHITE		Š 	Conditions	A A	ninis	stere	d as	Administered as a dry powder.		Subject skin and test compound	in and te	set com	punod	
						ster	ed v	1th	physiolo	gical sal	moistened with physiological saline prior to subject exposure.	to subje	sct exp	osure.	
			Onset of	of signs		, III	(s), mortality		(m)	Mort	Mean	Mean	Mean Body Wts.	ts. (kg)	
Dosage	Conc		Ä	Hours			ρΩ	Days		Cumula-	Body Wt.		Days		
9/kg	*	0-4	4-12	12-24	2	3	4 5	9	7 8-14	tive	Init Fin	1	3 17	14	
				┖	,	\vdash	-]	\ ::	1	3.38	3.43 3.47	7 3.58	
					7-2				₹	T/4		±. 35 ±. 17 ±. 33 ±. 32 ±. 35	33 ±.3	2 4.35	
							-		Ξ			3.38 3.48 3.	3.40 3.35	5 3.38	
3.2	_				S-2					1/4		±.08 ±.15 ±.	1.22 1.17	7 ± .08	
						┞	-				3.35	3.17 3.	3.05 2.9	8	
10.0				¥-1	S-3 M-	Ŧ		_	¥-2	4/4	3.25	±.18	1.07 1.11	1	
Control						-	-		_	_	3.68 3.81	3.68	3.69 3.71	19.81	
Wrapped Oaly	ly							_		9/4	1.21 1.20	$\pm .20 \pm .21 \pm .$	±.21 ±.23	3 ±.20	
							┼-		_						
						1	┼		-			ļ	-		
							-						-		
Signs of i	intoxication:	1 :	Skin a	Skin areas necrotic with edema.	rotic	v.	h.	ema.							

The urinary Gross autopsy: One rabbit at 3.16 gm/kg dosage showed caseous white material in colon wall at unction of free particles of 1/16" diameter of caseous material in the urinary bladder. bladder was thickened and the left kidney was adhered to the pertoneum.

*Probit analysis by the method of Bliss

40 CFR 162 Toxicity Category III Lot 0611-1, 10/75 Chemical Compounding Corp. Riverhead, L.I., N.Y.

APPENDIX EE

COMPOUND:	l	ed Mix	ture o	Powdered Mixture of Pacakges "A"	jes ",	ag .	and "	"B"		USAEH	A STUDY N	USAEHA STUDY NO. 75-51-1095-84	1095-	\$			
			ន	LD50* 2.61 g/kg	7 19	Į,	۱			2 \$€	.L. 1.1	95% C.L. 1.1 - 6.2 g/kg	9				
ACUTE DEI	ACUTE DERMAL LDSO		SI	Slope 7.6	,		ì			S.E. 64	64					•	
NEW ZEALA	NEW ZEALAND WHITE		<u>ତି</u> 	Conditions Administered as a Wet paste.	Admi	nist	erec	A AS	X	et pa		Subject skin and test compound	n and	test c	nodwo	nd	١
					mois	tene	3	ith	hys	iologi	cal sali	moistened with physiological saline prior to subject exposure	to sub	ject e	nsodx	re.	
			Onset of	of sign	signs (s), mortality (m)	Ę,	rta	lity	(E)		Mort	Mean	<u>}</u>	Mean Body Wts.	y Wts	(kg)	
Dosage	Conc		Но	Hours	_		Δ	Days			Cumula-	Body Wt.		Days	s		
g/kg	*	0-4	4-12	12-24	2	3	4 5	9	7	8-14	tive		1	3	7	14	
10.0				<u> </u>	M2	-						3.05 -	3.06	1	ı	1	
3.2				72	\$4	표	-	_			3/4	1	2.55 2.77	2.50 2.50	2.50	2.55	
1.0				_	84	豆	├				1/4)	2.93 2.81	2.93 2.81 2.73 2.78 2.93	2.78	2.93	
0.32					84		├-	 			0/4	2.80 2.5 +.15 +.2	2.56 2.73 ±.25 ±.13	2.56 2.73 2.55 2.51 2.56 ±.25 ±.13 ±.15 ±.25 ±.25	2.51 ±.25	2.56	
Control Wrapped Only	V1.		<u> </u>				-	-			0/4	}	2.86 ±.28	2.83 2.83 1 ±.28 ±.28	2.83 2.83 3.03 1.28 1.28 1.24	3.03 ±.24	
						 											T. Titam
						 											
										-							
Giona of Interviews	7.400	l	1				ب ا									!	}

Signs of Intoxication: Skin areas necrotic with edema.

normal livers. Kidneys from these rabbits were fatty or diffusely hemorrhagic with casts (blood) Rabbits that died during test had fatty congested livers and large red infarcts of the kidneys. Rabbits that survived had fatty livers, or early cirrhotic changes (nodular hyperplasia) or Gross autopsy:

in the pelvis or normal kidneys.

40 CFR Toxicity Category III

* Probit analysis by the method of Bliss. ** Lot 0611-1, 10/75, Chemical Compounding Corp, Riverhead, L.I., N.Y.

APPENDIX FF

COMPCUND:	Disinfectant	1	d'xture	mixture, complete with KI,	ete wi	th KI,	Wet		USAEH	USAEHA STUDY NO.	10. 75-51-0195-84	195-84			
			1.050		>31.6 ml/kg	K 9			954 C.L.	12.		1			
ACUTE DERMAL LDSO	TE DERMAL LDSO		Slope	pe					ສຸ			i		•	
NEW ZEALAND WHITE	ND WHITE		Co	Conditions Water slurry of	Water	sluri	75	Ö	complete	disinfec	disinfectant mixture	•	at a concentration of	ation	30
			Oncet	of cions	Tm/6m c7	mortality	111			Morr	Mean	Mean	Body Wts.	(ka)	
Dosage	Conc		Hours		1		Days			Cumula-	Body Wt.	1	Davs		
m1/kg	•	9-0	4-12	12-24	2 3	4	5 6	2	8-14	tive		-	2 3	9	14
						-	-	_			2.88 3.11	2.78 2.	2.83 2.92	2.88	3.11
1.0	2.5						-			0/4	- 1	±.38 ±.33		1.22	
					-		-				3.33	3.13	08 3.14	3.05	m
3.16	2.5									0/4	±.15	±.15		±.20	±.15
							-	_			2.99	2.73 2.13	13 2.68	2.73	2.
10.0	2.5					_				0/4	±.30	±.26 ±.	±.10 ±.28	±.19	
			_				-	_				2.70 2.	2.53 2.58	2.61	2.99
31.6	2.5									0/4	±.17 ±.21	±.22 ±.	±.19 ±.23	1.17	1.21
			_			L	\vdash	<u> </u>				2.60 2.	2.68 2.74	2.78	3.04
Control					_		_	_		0/4	±.33 ±.23	±.34 ±.	±.29 ±.29	±.29	±.23
															
			_				-	_					_		
					1	7	+	_				-	-		
					1	-	\dagger	_				-	-		
						-									
Signs of	Signs of intoxication:	ion:	Skin i	Skin irritation was evident at all dosage	on was	evid	ent	t a	11 dosa	ige levels	s 24 hours after		application	no	
preducing	producing within seven		lays se	days severe to primary irritation.	prima	ry in	ritat	ion	•	,					
Gross Autopsy: and tissues at		u	itatio Ifter e	ritation at 14 days had progressed after exposure.	days	had pi	rogre	ssec	to e	to eschar formation.		change	No changes in organs	ens	
											-				

* Probit analysis Bliss, C.I. (1952) The Statistics of Bioassay, Vol II Academic Press, N.Y. 40 CFR 162 Toxicity Category IV

APPENDIX GG

COMPOUND: Package "A"**	Package	"A"**	Pormu	Formula of Disinfectant	sinf	ecta	it l			USAE	USAEHA STUDY NO. 75-51-0195-84	vo. 75-	51-01	95-84				
	,		Ç	LDEA* 2.65 9/kg	5 9/	<u>1</u>				956	95% C.L. 1.2 - 5.9 q/kg	- 5.9 q/	kg	1.				1
ACUTE DERMAL LD50	AL LDS0		Slo	Slope 8.24	4					ស ភ	S.E. 127						•	
MALE RABBITS NEW ZEALAND WHITE	BRITS O WHITE		Co	Conditions Administered as wet paste.		mini	ste	red	as	wet pa	ste. su	Subject skin and test compound	in ar	d te	St CO	unodu	70	T
					OH	iste	ned	wit	디디	hysiol	moistened with physiological saline prior to subject exposure	line pri	or to	विह	ject	Bodxa	ure.	
			Onset of	of signs		E,	ort	(s), mortality (m)	ت بر	ê	Mort	Mean	_1	Mean	Mean Body Wts.	Wts.	(<u>kg</u>	1
_	Conc		Hours	ırs				Days			Cumula-	Body Wt.	اند		Days			
g/kg	*	0-4	4-12	12-24	2	3	4	5 6	17	5 6 7 8-14	tive	Init	Fin	1	3	7	14	
· ·						_		-	-	_	0/4		3.64		3.18 3.18 3.64	3.18	3.64	
- o: 1						_			_			±.34	±.36 ±.34		±.36 ±.42 ±.36	±.42	÷.36	
				Æ			\vdash	-	-	_	,,,	3.75	3.90 3.87		3.80 3.85 3.90	3.85	3.90	AT-10
3.2				S2	A 2			_			3/4	1.31	±.00 ±.12	. 12	1.00 1.00 1.00	₹.00	+.00	
10.0					Γ		<u> </u>	냔	-]	***	3.53	-	3.43	3.60 3.40	3.40	•	
				54	S2	T _S		<u> </u>		ш	4/4	±.24		±.17	-		-	1
Control									_		0.74		4.35	3.88			4.35	:=
wrapped only	.v								\dashv		• /2	±.50	±.52 ±	9	÷.5	1.51	±.52	T
										i,								
						Ŀ		-							 			
									 									
						_				-								
							1	İ	1					I				

One rabbit at 1 mg/kg in the Gross autopsy: Two animals showed probable compound related changes at necropsy. One rabbit had kidneys that were grossly pale and friable. The other animal at 3.2 mg/kg had free blood abdominal cavity with fibrin tags on the viscera but with no evidence of perforated viscera. Nasal discharge, skin areas necrotic with edema. Signs of intoxication:

40 CFR 162 Toxicity Category III

*Probit analysis by the method of Bliss. ** Lot 0611-1, 10/75 Chemical Compounding Corp., Riverhead, L.I., N.Y.

APPENDIX HH

COPPOUND:	COPPOUND: Trichloromelant	elamine				USAE	USAEHA STUDY NO. 75-510195-84
GUINEA PIG	GUINEA PIG SENSITIZATION	rion	sqns	Substance: Tri	Trichloromeiamine	mine	
HARTE	HARTLEY STRAIN		Iden	Identity: Intra of 0. Positive Contro	dermal inj 1 ml of a 1 - Dinitr	ection - 0.1% so ochlorob	Identity: Intradermal injection - Ten sensitizing doses of 0.1 ml of a 0.1% solution in saline
	Moan Body Baight (a)	deight (g)	Diluent	+	Test Compound	punodw	
24 Hrs	Initial	Final	Initial	Final	Initial	Final	Comments
fest Cmpd	286 ±39	478 ±50	0	0	3	17	Test compound did not produce
Positive	330	518	0	0	37	262	a sensitization reaction in onlinea pics.
CONCEST	Mean Rody Meight (a)	Saight (a)	Diluent	int	Test Compound	punodu	
H.8 Hrs	Initial	Final	Initial	Final	Initial	Final	DNCB positive control showed a
Test Ompd			0	0	0	0	sensitizing reaction in 10/10 guinea pigs.
Constant			0	0	4	285	Final Scores
							<pre>> 100 strong sensitizing 25-100 mild sensitizing < 25 no sensitization</pre>

The Landsteiner Guinea Pig Sensitization Test.

APPENDIX II

CONSOGNO	: Complete d	COMPOUND: Complete disinfectant mixture with KI	mixture with	ı KI		USA	USAEHA STUDY NO. 75-51-0195-84
GUINEA PI NA HARTLE	Guinea Pig Sensitization Nale Hariley Strain	TION	Sub: Posi Ider	Substance: Dis Positive Contro Identity: Intr	Disinfectant mixture, ontrol: Dinitrochlorober Intradermal injection. ml of a 0.1% solution	mixture, ochlorob	Complete wingene Concentrate C
				each	each day of injection,	jection.	
	Mean Body Weigh	Weight (g)	Diluent	ñ	Test C	Test Compound	
24 Hrs	Initial	Final	Initial	Final	Initial	Final	
Test Cmpd	286 ±32	463 ±28	0	0	æ	13	Test commond at a
Positive Control	292 ±29	449	0	0	19	313	a sensitization reaction in quinea pios.
48 Hrs	Triffal For	weight (g)	Diluent	ınt	Test Compound	punodu	down
Test Cmpd		10111	0	Final 0	Initial 0	Final 6	a sensitizing reaction in
							to the guinea pigs.
Control			0	0	6	221	Final Scores
							> 100 strong sensitizing 25-100 mild sensitizing

The Landsteiner Guinea Pig Sensitization Test

APPENDIX JJ

COMPOUND	: Package"A	COMPOUND: Package"A*" Formulation of Disinfectant	n of Disinfe	ectant		USA	USAEHA STUDY NO. 75-51-0195-84
GUINEA PI	GUINEA PIG SENSITIZATION . HALE	TION	sqns	Substance: Pe	Package "A"	·	
HARTE	HARTLEY STRAIN		Ider	Identity: Ir	Intradermal injection. Ten sem	njection	. Ten sensitizing doses of 0.1
			Posi	tive Contr	ol: Dinita	ochloro	Positive Control: Dinitrochlorobenzene (DNCB)
	Mean Body Weight (g)	Weight (q)	Diluent	ñ	Test Compound	mpound.	
24 Hrs	initial	Final	Initial	Final	Initial	Final	Comments
Test Cmpd	205 36	399 48	0.0	8.0	0.0	0.0°	Test compound did not produce a
Fositive	241 ± 51	465 ± 1e 7	0.8	0.0	22.0	421.0	sensitization reaction in guinea pigs.
	Mean Body Weight (g)	Veight (g)	Diluent	nt	Test Compound	punoqu	
FB Hrs	Initial	Final	Initial	Final	Initial	Final	DNCB positive control showed a
Test Cmpd	•	1	0	æ	0	0	
Positive Control	•	•	0	0	12	198	Final Scores
The Landsteiner	1	Guinea Píg Sensit	Sensitization Test	4			>25-100 mild sensitizing <25 no sensitization
- 22 4 - 4							

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APPENDIX KK

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